



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
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September 16, 2014

BECKMAN COULTER, INC.  
NANETTE CANEPA  
STAFF REGULATORY AFFAIRS  
250 S. KRAEMER BLVD., MAIL CODE E1.SE.01  
BREA CA 92821

Re: K140496

Trade/Device Name: Access Vitamin B<sub>12</sub> Assay  
Access Ferritin Assay  
Access Folate Assay  
Access HYPERsensitive hTSH Assay  
Power Express Sample Processing System Generic Connection  
Module

Regulation Number: 21 CFR 862.1810

Regulation Name: Vitamin B<sub>12</sub> test system

Regulatory Class: II

Product Code: CDD, DBF, CGN, JLW, JJE

Dated: August 14, 2014

Received: August 18, 2014

Dear Ms. Canepa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.  
Director  
Division of Chemistry and Toxicology Devices  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (*if known*)

k140496

Device Name

Power Express Sample Processing System with Generic Connection Module and Access Immunoassay System Reagents

### Indications for Use (*Describe*)

The basic Power Express is an automated sample handling system which processes sample tubes from the pre-centrifugation, pre-sorting step to presentation of centrifuged and decapped samples into Generic or Personality Racks for specific instruments. The Power Express can be configured with optional software and hardware to allow processing of sample tubes on Generic Connection Instruments. The Power Express performs all pre-analytical sample tube preparation, and then sorts the sample tubes directly to Generic Connection Modules where the samples are pipetted by the Generic Connection instrument for testing. After the samples are pipetted, the tubes can route to other instruments for additional testing or to Outlet Racks.

The UniCel DxI 800 Access Immunoassay System with laboratory automation connection is a microcomputer-controlled, random and continuous access analyzer that includes an external computer. This computer stores the system user interface (UI) software and allows the operator to interface with and direct the instrument software. The UniCel DxI 800 System uses enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection) for determination of various analytes, such as Vitamin B12, Ferritin, Folate and hTSH along with other various enzyme immunoassays assays that may be adaptable to the analyzer depending on the reagent used to induce the enzyme immunoassay reaction. The UniCel DxI 800 System is an in vitro diagnostic device for use in the clinical laboratory.

The Access Ferritin assay is a paramagnetic particle, chemiluminescent assay for the quantitative determination of ferritin levels in human serum and plasma (heparin) using the Access Immunoassay Systems. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism.

The Access Folate assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of folic acid levels in human serum, plasma (heparin) and red blood cells using the Access Immunoassay Systems. Folic acid measurements are used in the diagnosis and treatment of megaloblastic anemia.

The Access HYPER sensitive hTSH assay is a paramagnetic particle, chemiluminescent assay for the quantitative determination of human thyroid-stimulating hormone (thyrotropin, hTSH) levels in human serum using the Access Immunoassay Systems. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

The Access Vitamin B12 assay is a paramagnetic particle, chemiluminescent assay for the quantitative determination of vitamin B12 in human serum and plasma (heparin) using Access Immunoassay Systems. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.

Type of Use (*Select one or both, as applicable*)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**510(k) Summary**

Power Express

**1.0 Submitted By:**

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**2.0 Date Submitted:**

September 12, 2014

**3.0 Device Name(s):**

**3.1 Proprietary Name**

Access Vitamin B12 Assay  
Access Ferritin Assay  
Access Folate Assay  
Access HYPERsensitive hTSH Assay  
Power Express Sample Processing System Generic Connection Module  
and Access Immunoassay System Reagents

**3.2 Common Name**

Access Vitamin B12 Assay  
Access Ferritin Assay  
Access Folate Assay  
Access HYPERsensitive hTSH Assay  
Laboratory Automation System

### 3.3 Classification Name

Name	Regulation Number	Product Code	Device Class	Review Panel
Vitamin B <sub>12</sub> test system	862.1810	CDD	II	Clinical Chemistry
Ferritin immunological test system	866.5340	DBF	II	Immunology
Folic acid test system	862.1295	CGN	II	Clinical Chemistry
Thyroid stimulating hormone test system	862.1690	JLW	II	Clinical Chemistry
Discrete photometric chemistry analyzer for clinical use	862.2160	JJE	I	Clinical Chemistry

### 4.0 Predicate Device:

The Power Express claims substantial equivalence to the Power Processor Sample Processing System with Generic Connection Module V5.0 currently in commercial distribution, FDA 510(k) Number K110413.

Candidate(s)	Predicate	Manufacturer	Docket Number
Power Express	Power Processor Sample Processing System with Generic Connection Module V5.0  Access Ferritin Assay Access Folate Assay Access HYPERsensitive hTSH Assay Access Vitamin B <sub>12</sub> Assay	Beckman Coulter, Inc.	K110413

### 5.0 Description:

The Power Express is Beckman Coulter's Power Processor Sample Processing System with the modifications noted in this premarket submission. The Power Express and the Power Processor Sample Processing System are scalable laboratory automation systems (LAS) designed to streamline peri-analytical processes in the clinical laboratory.

The Power Express is an automated sample handling system which processes sample tubes from the pre-centrifugation, pre-sorting steps to presentation of centrifuged and decapped samples into racks for chemistry, immunoassay, hematology, and coagulation systems. The Power Express is designed to free laboratory personnel from biohazard exposure and routine sample preparation.

The Power Express software can be configured with optional hardware to allow processing of sample tubes on physically connected analyzers using common communication protocols (Generic Connection Instruments). The Power Express performs pre-analytical sample tube preparation then sorts the sample tubes directly to the optional hardware interface between the LAS and analyzer (Generic Connection Module) where the samples are pipetted by the analyzer for testing. After the samples are pipetted, the tubes can be routed to other instruments for additional testing or to Outlet Racks.

A basic Power Express System is comprised of a Line Control Computer, a system console with Cennexus software, Inlet Module, Centrifugation Module, Decapper Module, track transport system and Outlet Module. Additional modules may be added for aliquot capability, sample capping, and ambient or refrigerated storage.

## 6.0 **Indications for Use:**

The basic Power Express is an automated sample handling system which processes sample tubes from the pre-centrifugation, pre-sorting step to presentation of centrifuged and decapped samples into Generic or Personality Racks for specific instruments. The Power Express can be configured with optional hardware to allow processing of sample tubes on Generic Connection Instruments. The Power Express performs all pre-analytical sample tube preparation, and then sorts the sample tubes directly to Generic Connection Modules where the samples are pipetted by the Generic Connection instrument for testing. After the samples are pipetted, the tubes can route to other instruments for additional testing or to Outlet Racks.

The UniCel DxI 800 Access Immunoassay System with laboratory automation connection is a microcomputer-controlled, random and continuous access analyzer that includes an external computer. This computer stores the system user interface (UI) software and allows the operator to interface with and direct the instrument software. The UniCel DxI 800 System uses enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection) for determination of various analytes, such as Vitamin B12, Ferritin, Folate and hTSH along with other various enzyme immunoassays assays that may be adaptable to the analyzer depending on the reagent used to induce the enzyme immunoassay reaction. The UniCel DxI 800 System is an in vitro diagnostic device for use in the clinical laboratory.

The Access Ferritin assay is a paramagnetic particle, chemiluminescent assay for the quantitative determination of ferritin levels in human serum and plasma (heparin) using the Access Immunoassay Systems. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism.

The Access Folate assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of folic acid levels in human serum, plasma (heparin) and red blood cells using the Access Immunoassay Systems. Folic acid measurements are used in the diagnosis and treatment of megaloblastic anemia.

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The Access Vitamin B12 assay is a paramagnetic particle, chemiluminescent assay for the quantitative determination of vitamin B12 in human serum and plasma (heparin) using Access Immunoassay Systems. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.

**7.0    Comparison to the Predicate:  
(Description of the Modification to the Legally Marketed Device)**

The modifications to the Power Processor include an upgrade to the process control software and upgrades to the hardware which were implemented using Beckman Coulter design controls. The list of similarities and differences between the Power Processor and the Power Express are listed in the table below.

The following table provides a summary of the similarities between the Power Express and the Power Processor.

<b>Aspect / Characteristic</b>	<b>Power Processor Sample Processing System with Generic Connection Module Software Version 5.0 (K110413)</b>	<b>Power Express</b>
Intended Use	<p>The basic Power Processor is an automated sample handling system which processes sample tubes from the pre-centrifugation, pre-sorting step to presentation of centrifuged and decapped samples into Generic or Personality Racks for specific instruments.</p> <p>The Power Processor can be configured with optional software and hardware to allow processing of sample tubes on Generic Connection Instruments. The Power Processor performs all pre-analytical sample tube preparation then sorts the sample tubes directly to Generic Connection Modules where the samples are pipetted by the Generic Connection Instrument for testing. After the samples are pipetted, the tubes can route to other instruments for additional testing or to Outlet Racks.</p>	Same (replacing the name with Power Express)
System Design	Open LAS architecture enables multiple analyzer connections, including 3 <sup>rd</sup> party systems. Scalable, modular configuration.	Same
Sample Transfer Method	<p>Onboard sampling is the physical transfer of the sample tube/rack from the automation track to the analyzer's sample load and identification area.</p> <p>Outboard sampling capability using the analyzer's existing LAS communications interface and Generic Connection Module.</p>	Same
Fundamental Technology	Centralized operation and monitoring of decentralized equipment.	Same
Chemistry Analyzer Connection	Unicel DxI 800 Access Immunoassay System	Same
Assay Performance	Access Ferritin Assay Access Folate Assay Access HYPERsensitive hTSH Assay Access Vitamin B12 Assay	Same

The following table provides a summary of the differences between the Power Express and the Power Processor.

<b>Aspect/ Characteristic</b>	<b>Power Processor Sample Processing System with Generic Connection Module - Software Version 5.0</b>	<b>Power Express</b>
System Modules	The basic Power Processor System is comprised of a line controller computer, a system console with PrepLink™ software, inlet module, hematology module, centrifugation module, decapper module, track transport system, and output module. The Generic Connection module is an optional module to enable analyzer connectivity.	Same, except for <b>replacement of PrepLink software with Cennexus.</b>  No hematology module.
Sample Identification	Identification of patient tubes and sample programming using bar codes.	Same, <b>except for tube tracking using short range RFID readers detecting embedded chips in the sample carrier.</b>
Sample Handling	Processes multiple tube sizes/types simultaneously; sorts and maps samples for routing, storage, and retrieval; performs intelligent sample routing based on system status for LX/DxC/IDC (Dxi), connections. Generic connection modules process only a single tube size.	Same, except Beckman Coulter LX and DxC instruments are connected using the Generic connection interface
Operating Environment	Operating Software Microsoft Windows XP, Computer Console with Single User Interface.	Operating Software Microsoft Windows 7 Computer Console with Single User Interface
Host Communications	The ability to interface with a LIS device to receive patient identification and test requests via a communications protocol to provide sample tracking via bar code labeling.	ASTM protocol with LIS Defined aliquots and Host Query.
Throughput	450 tubes per hour (with 2 centrifuges).	1200 tubes per hour (with 4 centrifuges), and addition of 2 lanes/ track to manage more carriers at same track velocity.
Control panel	Buttons and 2 character display.	Touch screen based control on each module GUI with LCD.
Cyber security	Field Service Engineers login with password.	Field Service Engineers, Users, Supervisors login with password.

<b>Aspect/ Characteristic</b>	<b>Power Processor Sample Processing System with Generic Connection Module - Software Version 5.0</b>	<b>Power Express</b>
		Microsoft Defender for anti-spyware.  Fault tolerant capability with dual modules for the critical hardware functions.
Racks per Inlet	4 racks that hold 50 tubes each.	Up to 8 racks that hold up to 50 tubes each.
Storage units	3 storage units of the same type.	Up to 4 ambient or refrigerated storage units.
Centrifuge	Tube sizes must be all the same.	Supports mixed tube sizes.
Inlet/Outlets	200 tubes No drawer – open platform.	400 tubes Access through drawers (2 drawers in each of the inlet/outlets).
Track lanes	2 lanes.	4 lanes.
Aliquotter	Manual tray filling Single System defined secondary tube labeling.	Bulk feeder Dual units System and LIS defined secondary tube labeling.
Centrifuges	2 centrifuges.	4 centrifuges.
Primary Decapper	Single unit (Rocker).	Dual unit (Rotary).
Secondary Decapper	Single unit (Rocker).	Single unit (Rotary).
Recapper	Single unit.	Dual unit.

## **8.0 Summary of Performance Data:**

Based on the risk analysis, the modifications to the Power Processor did not introduce any new risks to the performance of the assays through the chemistry analyzer connections; therefore there was no requirement for Verification and Validation Testing.

To address the modifications to the Power Processor, performance data from verification and validation testing demonstrated that all software design, development and verification activities have been completed and passed to support equivalency of Power Express to the Power Processor V5.0 Sample Processing System. Evidence is demonstrated through

Software design testing of:

- Sample Management
- Data Management
- Set-up
- Analyzer Connections
- Host Interface Communications
- Communication with Line Control Software
- Sample Routing Logic
- Sample Storage
- Error Recovery

System verification and validation testing of:

- System Functions
- System operations
- Maintenance
- Error conditions
- Error codes
- Problem description and solution in the system instructions for use

## **9.0 Conclusion:**

As summarized, the Power Express is substantially equivalent to the originally cleared Power Processor Sample Processing System. Performance testing of the device demonstrates that the device functions as intended, meeting the requirements of the design specifications. The changes to the device do not constitute a new intended use and any differences in technological characteristics have been tested to demonstrate that the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness.

The 510(k) summary is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.